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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,633	12/19/2001	Daniel D. Gallaher	600.523US1	4606
21186	7590	05/04/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			PAGE, THURMAN K	
			ART UNIT	PAPER NUMBER
			1615	
			DATE MAILED: 05/04/2004	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,633

Applicant(s)

GALLAHER ET AL.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74, 97 and 98 is/are pending in the application.
- 4a) Of the above claim(s) 75-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74, 97 and 98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's amendment and response, filed December 15, 2003.

Acknowledgement is made of the addition of new claims 97 and 98.

Claims 1-74, 97 and 98 are pending in this action.

Response to Arguments

Applicant's arguments filed December 15, 2003, have been fully considered but are not persuasive. The rejection of record of claims 1, 6, 9, 22-24, 36 and 37 under 35 USC 102(b) over Pinto (WO 98/50398) is maintained. Applicant argues that the cited prior art reference fails because it does not teach a method of reducing the percentage of body fat in a mammal comprising administering a sufficient amount of hydroxypropyl methylcellulose to the mammal for a time sufficient to reduce the percentage of body fat in the mammal. Examiner disagrees with applicant's reading of the prior art. The prior art teaches the administration of a composition comprising beta-glucans wherein the beta-glucan composition slows the rate of gastric emptying, reduces the rate of carbohydrate absorption and absorbs and eliminates fats in the gut

(page 1, lines 22-26). Reducing and/or eliminating fat absorption at its source -- in the gut -- thwarts body fat production/creation. Accordingly, it is the position of the examiner that the Pinto reference anticipates claims 1, 6, 9, 22-24, 36 and 37.

The rejection of record of claims 1-6, 9, 13, 24 and 27 under 35 USC 102(b) over Jamas et al (US 6,143,731), is maintained. Applicant argues that the cited prior art reference fails because it does not disclose that the beta glucan supplement can reduce the percentage of body fat. Examiner disagrees with applicant's reading of the prior art. The prior art teaches that the amount of whole beta-glucan administered to an individual to promote weight loss or reduce weight gain should be that amount necessary to aid digestion, increase fecal wet weight, speed transit time of undigested food and insure the proper working of peristaltic muscles (column 6, line 65 bridging column 7, line 3). It is the position of the examiner that by speeding the transit time of undigested food, foods high in fat content will not reside in the gastrointestinal tract to be later metabolized into adipose tissue. Thus, the expected result is a reduction in body fat. Accordingly, it is the position of the examiner that the Jamas reference anticipates claims 1-6, 9, 13, 24 and 27.

The rejection of record of claims 1, 6 and 22 under 35 USC 102(e) over Fleischner (US Publication 2003/0039708 A1) is maintained. Applicant argues that the cited prior art reference fails because it does not teach that administration of the composition can lead to reduction in the percentage of body fat. The prior art

teaches that the disclosed formula increase fat loss as well as reduces weight (paragraph [0006]).

The rejection of record of claims 38, 41 and 50 under 35 USC 102(e) over Portman (US Publication 2002/0019334 A1) is withdrawn.

The rejection of record of claims 1-37 and 52-74 under 35 USC 103(a) over Jamas in view of Pinto or Portman, is maintained. Please refer to the discussion above related to Jamas and Pinto. Similarly, the rejection of record of claims 38-51 under 35 USC 103(a) over Portman in view of Bahram, is maintained. Portman teaches weight loss due to increased feelings of satiety obtained by administering a composition composed of soluble fibers such as HPMC. It is the position of the examiner that it is well known within the pharmaceutical arts that the administration of fiber containing compositions aid in the elimination of high fat content foods from the digestive tract. Accordingly, by thwarting or eliminating fat absorption, the subject in need of the composition inherently experiences a reduction in body fat.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-37, 52-74, 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al (US 6,143,731) in view of Pinto (WO 98/50398) or Portman (US Publication 2002/0019334 A1). The claims are directed to methods of reducing the percentage of body fat in a human via administration of indigestible, viscous polysaccharides, beta-glucans and hydroxypropylmethylcellulose. The method also includes reducing the level of leptin in the bloodstream of a mammal using indigestible polysaccharides.

In view of the 102(b) discussion of Jamas, the reference further teaches that the beta-glucan containing composition can be included as part of a complete nutritional food (column 7, line 13). While Jamas does not enumerate specific examples of the

food items, Pinto demonstrates, however, that beta-glucan-containing foods can be developed into cereals, snacks, pasta and yogurt (Pinto, page 6, lines 15-19). It would have been obvious for one of ordinary skill in the art to formulate this composition into various edible embodiments such as cereals or snacks, thus providing a range of possible alternatives for the subject in need of the composition.

Pursuant to Example 12 (column 15 bridging column 16), the test subjects that were administered the whole glucan diet, demonstrated weight loss results during a 20-day regimen. A 20-day regimen is equivalent to approximately 3 weeks. Referring to Table 11, the diet group fed whole glucan experienced weight loss equivalent to approximately 21 grams -- 21 grams translates into approximately an 18.8% reduction (column 15, Table 11).

Portman teaches a nutritional composition comprised of soluble fibers such as hydroxypropylmethylcellulose (page 4, paragraph 0059). The soluble fibers are present in the range of 0.10 to 5.0 grams, more preferably in the range of 1.0 to 4.0 grams (page 4, paragraph 0060). Portman discloses that there was a weight loss effect demonstrated over a period of 6 weeks (page 7, paragraphs 0095-0106). The disclosed composition may be used as a food additive to foods selected from the consisting of yogurt, jello, applesauce, cottage cheese, cereal, bread and candy bars (page 7, paragraph 0084).

The cited prior art patent does not expressly teach a reduction in leptin, however, studies have shown that there is a positive correlation between leptin and body weight. Andrico et al (Human Reproduction, Abstract, August 2002) is provided to demonstrate that relationship. Accordingly, if the claimed beta-glucan composition can be utilized to reduce body fat, the same beta-glucan composition can be utilized to reduce the amount of leptin in the subject.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600